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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,168

03/21/2006

Kathleen Beach

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EXAMINER

SALIMI, ALI REZA

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

07/09/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,168	<b>Applicant(s)</b> BEACH ET AL.	
	<b>Examiner</b> A R. Salimi	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,6,8-17,20-22,43,51,56 and 62 is/are pending in the application.
- 4a) Of the above claim(s) 3,6,8,11-15,51,56 and 62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 9, 10, 16, 17, 20-22, and 43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/27/07</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I (Claims 1, 9, 10, 16, 17, 20-22, and 43) in the reply filed on 06/09/08 is acknowledged.

Claims 3, 6, 8, 11-15, 51, 56, and 62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups. Election was made **without** traverse in the reply filed on 06/09/2008.

**Applicants are reminded to cancel the claims to the non elected Group(s).**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9-10, 16-17, 20-22, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the intended nucleotide sequence that comprising an epitope of a naturally occurring human papillomavirus protein. This affects the dependent claims.

Claim 1 is vague and indefinite, the intended metes and bounds of the nucleic acid is not defined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9-10, 16-17, 20-22, and 43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Edwards et al (US Patent No. 6,306,397 B1).

The teachings and claims of the above cited patent clearly anticipate the broad limitations of the claimed invention. Edwards et al taught human papillomavirus proteins wherein the proteins induce a humoral and/or cellular immune response against human papillomavirus in a suitable host (see the abstract). They also taught the different forms and stages of papillomavirus infection including stages of cervical intraepithelial neoplasia (CIN) (see Column 1, lines 47-65). Edwards et al taught method of eliciting immune response against HPV in a host (see claims 21-24). And taught the nucleic acid sequences (see Column 3, lines 1-5, Example 3, Example 4). Applicants are reminded that limitation of 30 years of age and younger has no patentable weight, because Edwards et al broadly taught inducing immune response in a human host which comprises the intended age limit.

Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Still further, the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention. See, Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 9-10, 16-17, 20-22, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Ertl et al (US Patent No. 7,132,262 B2).

The teachings and claims of the above cited patent clearly anticipate the broad limitations of the claimed invention. Ertl et al taught method of preventing or treating HPV infection in human utilizing polynucleotide encoding HPV protein (see claims 10-11). In addition, they

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taught their composition were the ones that mostly found in nature (see Column 15, lines 40-61). They also taught utilizing micro particles for delivery of their composition (see Column 13, lines 58-66). Applicants are reminded that limitation of 30 years of age and younger has no patentable weight, because Ertl et al broadly taught inducing immune response in a human host which comprises the intended age limit.

Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Still further, the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention. See, Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004).

Claims 1, 9-10, 16-17, 20-22, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Webb et al (US Patent No. 6,726,912 B1).

The teachings and claims of the above cited patent clearly anticipate the broad limitations of the claimed invention. Webb et al disclosed administration of nucleic acid utilizing micro particles as delivery systems (see Claim 9, Column 5, lines 12-27, and Column 9, lines 5-15). Applicants are reminded that limitation of 30 years of age and younger has no patentable weight, because Webb et al broadly taught inducing immune response in a host which comprises the intended age limit.

Additionally, under inherency doctrine where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of anticipation has been established. See, In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). Still further, the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention. See, Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004).

No claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/A R Salimi/

Primary Examiner, Art Unit 1648

07/06/2008